



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1540]

Migraine: Developing Drugs for Acute Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Migraine: Developing Drugs for Acute Treatment.” The purpose of this guidance is to assist sponsors in the clinical development of drugs for the acute treatment of migraine. This guidance focuses on specific drug development and trial design issues that are unique to the study of drugs for the acute treatment of migraine. This guidance is intended to serve as a focus for continued discussions among the Division of Neurology Products, pharmaceutical sponsors, the academic community, and the public.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Eric Bastings, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4338, Silver Spring, MD 20993-0002, 301-796-1039.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Migraine: Developing Drugs for Acute Treatment.” The purpose of this guidance is to assist sponsors in the clinical development of drugs for the acute treatment of migraine. This guidance focuses on specific drug development and trial design issues that are unique to the study of drugs for the acute treatment of migraine. This guidance is intended to serve as a focus for continued discussions among the Division of Neurology Products, pharmaceutical sponsors, the academic community, and the public.

Migraine is a chronic neurovascular disorder characterized by recurrent attacks of often severe headache, typically presenting with nausea, vomiting, and sensitivity to light and/or sound. Pharmacologic approaches to the treatment of migraine include drugs to treat acute migraine attacks as they arise (acute treatment of migraine) and drugs to reduce the frequency of migraine attacks (preventive treatment). This guidance addresses the development program of drugs for the acute treatment of migraine, including trial population, trial design, dose selection,

efficacy endpoints, and statistical considerations. The guidance also discusses safety considerations, pediatric studies, and labeling considerations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing drugs for the acute treatment of migraine. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 201, 312, and 314 have been approved under OMB control numbers 0910-0572, 0910-0014, and 0910-0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

or <http://www.regulations.gov>.

Dated: October 15, 2014.

Leslie Kux,
Assistant Commissioner for Policy.

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